

## REMARKS

In the Office Action dated November 14, 2006, the Examiner rejected claims 4 and 9 under 35 U.S.C. § 112, second paragraph as being indefinite; rejected claims 1-8 and 10 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,200,200 to Veech; and rejected claim 9 under 35 U.S.C. § 103(a) as being unpatentable over Veech in view of U.S. Patent No. 5,383,324 to Segers et al ("Segers").

Claims 11-20 are currently pending in this application. By this Reply, claims 14 and 20 have been amended. No new matter has been added.

At the outset, Applicants point out that claims 1-10 were cancelled and new claims 11-20 added in a Preliminary Amendment filed on July 30, 2004. The Preliminary Amendment was received and acknowledged by the PTO, based on the fact that claims 11-20 appear in published U.S. Patent Application No. 2005-0224372-A1, published on October 13, 2005. In this Office Action, the Examiner appears to have incorrectly addressed cancelled claims 1-10. Applicants assume that the Examiner intended to address pending claims 11-20. Accordingly, to the extent the Examiner's rejections apply to pending claims 11-20, Applicants respond as such.

Applicants respectfully traverse the Examiner's rejection of claims 4(14) and 9(19) under 35 U.S.C. § 112, second paragraph as being indefinite. While the Examiner rejected claim 9(19) under § 112, claim 19 does not contain the term "substantially," as suggested by the Examiner. Claim 20, however, does contain the term "substantially." By this Reply, claims 14 and 20 have been amended to eliminate the term "substantially." Accordingly, Applicants respectfully submit that the Examiner's § 112 rejection is now moot. Thus, Applicants request that the Examiner withdraw this rejection.

Applicants respectfully traverse the Examiner's rejection of claims 1-8(11-18) and 10(20) under 35 U.S.C. § 102(b) as being anticipated by Veech. Veech does not disclose each and every element of claim 11, for example. The Examiner contends that Veech teaches "methods for the preparation of therapeutic solutions which contain dissolved therein at the time of use unstable metabolites of the type normally present in human blood plasma, and also to the field of filled storable containers useful for the storage of such solutions in unit dose forms. (See column 1, Lines 12-18)" (emphasis added). (Office Action at 2-3.) The Examiner further contends that Veech discloses plastic containers with a plurality of chambers wherein "[e]ach chamber holds one or a group of separable components which are admixed into a common solution by chamber wall rupture internally before solution use. (See column 1, Lines 60-67)." (Office Action at 3.) Applicants submit, however, that despite these alleged teachings, Veech still fails to disclose each and every element of claim 11. Moreover, Applicants assert that the Examiner misinterprets the teachings of Veech.

In particular, Veech does not disclose a flexible bag assembly having "a first predetermined volume of an aqueous sodium bicarbonate component solution, said first predetermined volume being provided in at least one of the at least first and second compartments; and a second predetermined volume of an aqueous acid component solution, said second predetermined volume being provided in at least another of the at least first and second compartments" (emphasis added), as recited in claim 11. Veech does not disclose maintaining two aqueous solutions in separate compartments within the same flexible bag assembly prior to mixing to form a "peritoneal dialysis, hemodialysis or replacement fluid," as recited in claim 11. Veech merely teaches

maintaining a master batch solution in one compartment, while maintaining a crystalline or particulate material in a second compartment, prior to mixing to form a ready-to-use solution.

Veech discloses that “such crystalline material is charged into the chamber 12 of a container as illustrated above in FIGS. 1 and 2. Thereafter, the chamber 12 is sealed and one liter of the solution above prepared is charged into chamber 11 of such container 10 of FIGS. 1 and 2.” (Veech at col. 7, lines 38-42.) Veech further teaches that “the two liters of solution in chamber 11 intermixes with the particulate solid composition in chamber 12 and solution readily occurs, thereby to provide the desired two liter dialysis solution which is ready for conventional administration.” (Veech at col. 8, lines 27-31.) Moreover, nowhere does Veech disclose or suggest mixing an aqueous bicarbonate solution with an aqueous acid solution, as recited in claim 11. Accordingly, claim 11 is allowable over Veech, because Veech fails to disclose each and every element of claim 11. Thus, claims 12-20 are also allowable at least due to their dependence from allowable claim 11.

Applicants also respectfully traverse the Examiner’s rejection of claim 9(19) under 35 U.S.C. § 103(a) as being unpatentable over Veech in view of Segers. Veech in view of Segers fails to teach each and every limitation of claim 19. The Examiner asserts that Segers teaches a “device [that] includes an exterior body. The exterior body can be made of any rigid or flexible material that is permeable to water and carbon dioxide.” (Office Action at 9.) As discussed above with respect to claim 11, however, Veech does not disclose or suggest “a first predetermined volume of an aqueous sodium bicarbonate component solution, said first predetermined volume being

provided in at least one of the at least first and second compartments; and a second predetermined volume of an aqueous acid component solution, said second predetermined volume being provided in at least another of the at least first and second compartments" (emphasis added), as recited in claim 11. Accordingly, Segers fails to overcome the above-mentioned deficiencies of Veech and claim 11 is allowable over these references. Therefore, claim 19 is allowable over Veech in view of Segers at least due to its dependence from allowable claim 11.


In view of the foregoing amendments and remarks, Applicant respectfully requests reconsideration and reexamination of this application and the timely allowance of the pending claims.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: February 14, 2007

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